K023052

OCT 11 2002

VARIAN
medical systems

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Premarket Notification [510(k)] Summary
as required by 21 CFR 807.92

Date summary was prepared:

September 12, 2002

Submitter's Name:

Varian Medical Systems, Inc.
3100 Hansen Way m/s F055
Palo Alto, CA 94304

Contact Person:

Linda S. Nash
Corporate Director, Regulatory Affairs and Quality Assurance
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Device Name:

Acuity

Classification Name:

Radiation therapy simulation system

Predicate Device:

Varian Ximatron C-Series Radiation Therapy Simulatory with Version 4.2 Software, K964138.

Product Description:

The Varian Acuity is a Radiation Therapy Simulator. Its main function is to provide the means of planning the subsequent treatment of patients on therapy machines capable of delivering tumorcidal doses of photons or electron to specific target volumes in the human body. It achieves this by providing low dose level x-ray images (either radiographic or fluoroscopic) to duplicate the therapy treatment fields, along with machine coordinates and patient positional information. It is capable of simulating single, multiple or dynamic treatment fields.

Some version of the Simulator will also be able to provide digital tomographic imaging and real-time image capture, viewing and enhancement.

The Acuity consists of a drive stand which supports a vertically rotatable gantry. The stand also provides a housing for much of the simulator's electronics and its 3-phase x-ray generator. The stand is itself supported on a sub-floor-level baseframe which also extends forward from the stands area to provide support and horizontal rotation for a patient support couch.

The gantry provides mounting for an x-ray tube and beam shaping collimator and diametrically opposite these, a detector support arm assembly. All of which can be positioned anywhere around the simulator's isocenter via rotation of the gantry.

The detector support arm is a robotic type mechanism providing support and positional adjustment for a flat panel digital image acquisition device and film cassette holder.

Mechanical movements of the simulator are controlled either from an in-room handheld pendant or from a control room console. In addition, control panels mounted on each side of the couch provide control of couch movements, laser lights and contain emergency off buttons.

Intended Use:

The Acuity Radiation Therapy Simulator is to be used in radiation therapy simulation, using a fluoroscopic and/or radiographic x-ray system for visualizing the volume to be

exposed during radiation therapy and confirming the position and size of the therapeutic irradiation field to be applied.

Technological Characteristics:

See the attached "Specification Comparison Chart", Tab G

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 11 2002

Ms. Linda S. Nash
Corporate Director, Regulatory
Affairs and Quality Assurnace
VARIAN Medical Systems
Oncology Systems
3100 Hansen Way
PALO ALTO CA 94304-1038

Re: K023052
Trade/Device Name: Acuity
Regulation Number: 21 CFR 892.5840
Regulation Name: Radiation therapy simulation system
Regulatory Class: II
Product Code: 90 KPQ
Dated: September 12, 2002
Received: September 13, 2002

Dear Ms. Nash:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

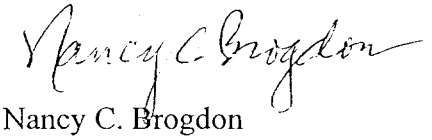
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K023052

Device Name: ACUITY

Indications For Use:

The Acuity Radiation Therapy Simulator is to be used in radiation therapy simulation, using a fluoroscopic and/or radiographic x-ray system for visualizing the volume to be exposed during radiation therapy and confirming the position and size of the therapeutic irradiation field to be applied.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓

(Optional Format 3-10-98)

David G. Jogerson

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K023052